EXHIBIT #7

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TVT, A New Surgical Procedure for the Treatment of Stress Urinary Incontinence

by Yitzhak Berger, M.D.

TVT, A New Surgical Procedure for the Treatment of Stress Urinary Incontinence

In the traditional PVS, 2 incisions (surgical openings) are required. In addition to the incision in the vagina, a second incision in the lower abdomen is needed in order to retrieve the sling material from the patient's own body. That results in a prolonged recovery, postoperative pain, requires 1-2 days of hospital stay and in most occasions the patient is discharged home with a catheter until she is able to urinate. In the past 1-2 years, a new sling procedure, called tension-free vaginal tape (TVT), was developed in Europe.

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TVT involves passing a synthetic tape around the urethra, through a small vaginal opening It is usually accomplished in 30-45 minutes and is performed under local, regional or general anesthesia. Patients are usually discharged home 3-4 hours after the surgery is finished and patients are usually discharged without a urinary catheter. Most patients resume normal activities in a few days.

In 1998, Dr. Berger was among the few American specialists who went to Sweden, on behalf of Gynecare of Johnson & Johnson, to assess this procedure.

Subsequently the clinical trial of the TVT commenced and the first TVT in the US was in fact done by Dr. Berger who now serves on the Medical Advisory Board of Gynecare and *Indigo of Johnson & Johnson. Dr. Berger is also a preceptor for the TVT and he teaches other physicians how to perform this surgery. Dr. Berger has performed over 130 TVT cases and he was invited to be a guest speaker on this new surgical procedure at the recent American Urological Association (AUA) meeting in Atlanta, Georgia (May 2000) and will present it in Singapore (October 2000) as well. In addition, the TVT data from Associates in Urology is being collected, along with other leading centers and will subsequently be published in professional magazines.

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LookSmart

Going Slow on Tension-Free Vaginal Tape Procedure

Sherry Boschert

SAN FRANCISCO - A new procedure being promoted to treat stress urinary incontinence--the tension-free vaginal tape procedure--should not be widely adopted until better data supporting its efficacy are available, two physicians cautioned at an ob.gyn. update sponsored by the University of California, San Francisco.

"We should encourage innovations, but these should not be clinically applied until they're adequately studied, at least with some type of controlled study," said Dr. Abner Korn, director of gynecology at San Francisco General Hospital.

Published reports on the Tension-Free Vaginal Tape (TVT) system consist of five case series involving a total of 200-300 patients, some of whom were followed up for up to 3 years.

These preliminary reports suggest that the TVT procedure has a short-term cure rate of 80%-90%. The minimally invasive procedure takes less than 30 minutes to perform and can be done under local anesthesia. The Food and Drug Administration approved TVT in January 1998 for the treatment of female stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

During the procedure, a prolene sling covered in a plastic sheath is passed under the midurethra to the rectus fascia on each side and is elevated just enough so that a cough stress test performed while the patient is still under local anesthesia produces minimal urine leakage.

The mesh sling is trimmed at the subcutaneous level and not secured to the fascia. Once the plastic sheath is removed, friction between the prolene tape and the narrow tissue canals created by the procedure initially hold the tape in place. Then fibrosis and tissue growth into the mesh is believed to help stabilize the tape.

Once adequate studies are conducted, the device could turn out to be quite valuable or it could be just another heavily promoted product that ends up hurting women as much as helping them, the speakers cautioned.

One surgeon who has performed the procedure, Dr. Vincent Lucente, said in an interview that the quality of the scientific evidence for any new drug or procedure is never ideal. Clinical experience has to build on it.

"But I'm very much convinced of the benefits of this procedure, and I tend to be a skeptic at heart," said Dr. Lucente, chief of the departments of gynecology and of urogynecology and reconstructive pelvic surgery at Lehigh Valley Hospital in Allentown, Pa. He is one of eight surgeons who were flown to Sweden by the product's U.S. distributor, Gynecare, a division of Ethicon in Somerville, N.J., to learn the procedure.

Data and scientific methodology are not the only considerations for patients seeking help for incontinence, said Dr. Lucente, who has been performing the procedure on U.S. patients for a year and is paid by Gynecare to teach it to other surgeons.

"It would be a disservice to our patients if we sat back and said we'll just wait 10-15 years until all the studies are done to the nth degree with the best methodology possible," he said.

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In a separate presentation at the update, Dr. Jeanette Brown of the University of California, San Francisco, agreed that adequate studies of the procedure need to be performed, and then she took the case series to task.

In the five published reports, no patients were lost to follow-up. "That never happens," suggesting that the reports include only "the patients they chose to tell us about, that they had complete data on," she said.

In addition, subjective and objective cure rates were the same in most of the studies. "I've never seen a series of trials that were so neat in which the data all matched so nicely," she added.

The reports also lack tables that would allow readers to analyze the data themselves, Dr. Brown said.

Complications occurred in less than 2% of patients in each report, but case series never reflect the true complication rate, she cautioned. For example, prospective cohort studies of the standard surgical procedures used to treat stress incontinence show complication rates of about 68%, compared with rates of 1%-5% in case series.

A patient's first surgery for stress incontinence has the best chance of working, and success rates decline severely with subsequent surgeries. Physicians should therefore demand good evidence of the risks and benefits of a new procedure before performing it on patients, Dr. Brown urged.

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Tension free vaginal tape (also known as TVT) was first introduced in Sweden in the mid 1990's by Ulf Ulmsten and Papa Petros. To date more than 150,000 patients worldwide (35,000 in U.S.) have been treated with GYNECARE TVT Tension-free support for incontinence. The majority of clinical studies suggest cure rates between 85-95%, most patients notice immediate improvement.

Dr. Miklos traveled to Sweden in October 1998, learned the operation and was the first surgeon in the Southeastern United States to perform the surgical procedure. Since that time approximately 200 surgeons have traveled to Atlanta to learn the surgical procedure from Dr Miklos. In October 2000 he was awarded the Golden Laparoscope Award at the 30th Annual American Association of Gynecologic Laparoscopists for his teaching video on the Tension free Transvaginal Tape procedure. To date he has performed almost 250 TVT operations and remains a national consultant and expert in its use.

TVT Transvaginal Tape Sling

- Simple 30 Minute Operation
- Two Miniature 1/3 Inch Incisions
- Outpatient Procedure
- Requiring Local Anesthesia
- 86 - 95% Cure Rate

How Does It Work?

The GYNECARE TVT Tension-free support for incontinence primarily consists of a mesh-like tape that is surgically inserted through the vagina to support the bladder neck and urethra, the tube through which urine exists the bladder. Ordinarily, the urethra maintains a tight seal to prevent involuntary loss of urine. For women with stress urinary incontinence, a weakened pelvic muscle floor or a defect in the urethral fascia cannot support the urethra in its correct position. If you undergo TVT surgery, your surgeon will restore the normal position of the urethra by weaving or placing a "sling" or mesh tape beneath it. Uniquely, TVT provides support at the middle of the urethra, the section that is under the most strain during normal activities. Placing the TVT in this area, therefore, helps restore this part of the urethra---instrumental to the urination process-- to a more natural position. Unlike other procedures, no bone anchors or sutures are necessary.

Patients deserve the most trusted and experienced care

Surgery

Surgery using the GYNECARE TVT usually takes approximately 20-30 minutes. While it can be performed under general anesthesia most of the studies performed recommend local or regional anesthesia (ie epidural or spinal). Many surgeons like Dr. Miklos has performed most his 200+ operations under local anesthesia with some intravenous sedation. Under local anesthesia the patient will be semi-awake, but will not feel the surgery. This allows the surgeon to evaluate whether the tape is providing adequate support by asking you to cough. Any necessary adjustments can be made right then and there. So, even before you leave the operating the room, the surgeon can usually determine if the procedure is successful. Performing this evaluation be fore the procedure is complete also reduces the need for using a urinary catheter, unlike other sling operations. Patients report minimal discomfort following surgery with the TVT for incontinence. In fact approximately 40% of Dr. Miklos' patients will not use any pain medication after being discharged from the hospital.

Surgical Technique

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